

Amendments to the Claims:

The listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1-10 (Cancelled)

11. (Withdrawn). A method of preparing a solid non-effervescent dosage form suitable for oral administration of a sodium salt of racemic ibuprofen comprising the steps of:

mixing a carrier material with the ibuprofen medicament under dry conditions, wherein the carrier material comprises 3-20% alkali metal carbonate or bicarbonate by weight of the dosage form, 10-50% [a] compressible filler component by weight of the dosage form and up to 15% of a disintegrating component by weight of the dosage form to obtain a mixture and then compressing said mixture into a solid non-effervescent dosage form having a crushing strength in the range 6.5-15Kp and a disintegration time of less than 10 minutes, wherein the sodium salt of racemic ibuprofen comprises at least 35% by weight of the dosage form.

12. (Withdrawn). The method according to claim 11 wherein the dosage form comprises 40-60% sodium salt of racemic ibuprofen by weight of the dosage form.

13. (Withdrawn) The method according to claim 11 wherein the carrier material is adapted for direct compression with said sodium salt of racemic ibuprofen into a tablet.

14. (Withdrawn) The method according to claim 12 to prepare a tablet wherein the compressible filler component comprises microcrystalline cellulose and the alkali metal carbonate or bicarbonate is sodium carbonate or bicarbonate.

15. (Withdrawn) The method according to claim 11 wherein the carrier material comprises 45-

60% microcrystalline cellulose, 2-10% croscarmellose sodium by weight and 2-20% sodium carbonate or bicarbonate by weight.

Claims 16-19 Cancelled.

20. (Withdrawn) A process to prepare a non-effervescent solid dosage form suitable for oral administration comprising a racemic ibuprofen medicament present to an extent of 35% or more by weight of the dosage form characterised by combining a carrier material comprising 8-80% compressible filler component by weight of the carrier 10-20% disintegrating component, by weight of the carrier, 8-40% alkali metal carbonate or bicarbonate by weight of the carrier, with the ibuprofen medicament to form a homogeneous solid mixture under dry conditions optionally with other tabletting excipients and compressing the mixture into one or more solid dosage forms having a crushing strength in the range 6.5-15K and a disintegration time of less than 10 minutes.

21. (Withdrawn) A process according to claim 20 wherein the ibuprofen medicament is a salt of racemic ibuprofen.

22. (Withdrawn) A process according to claim 20 wherein the carrier material comprises an inert diluent component.

23. (Withdrawn) A process according to any one of claims 20 wherein the dosage form is prepared by direct compression of a powder mixture of the ingredients and does not include any pre-granulation stage.

24. (Withdrawn) A process according to any one of claims 20 wherein the ratio of the alkali metal carbonate or bicarbonate to compressible filler component is in the range 2:1 to 1:10 parts by weight.

25. (Withdrawn) A process according to any one of claims 20 wherein the ratio of ibuprofen medicament to the carrier material is in the range 2:1 to 1:2 parts by weight and the carrier material comprises 5-20% sodium carbonate or bicarbonate by weight of the dosage form.

Claims 26-31 Cancelled.

32. (Withdrawn) The method according to claim 11 further incorporating the addition of up to 20% by weight of an inert diluent.

33. (Withdrawn) the method according to claim 11 wherein the tablet comprises 40-60% sodium salt of racemic ibuprofen by weight of the dosage form, 20-50% compressible filler component by weight of the dosage form, up to 10% disintegrating agent by weight of the dosage form, 4-16% sodium carbonate by weight of the dosage form, up to 4% stearic acid, calcium stearate or magnesium stearate by weight of the dosage form and up to 2% colloidal silicon dioxide by weight of the dosage form.

34. (Withdrawn) The method according to claim 12 to prepare a directly compressed tablet comprising 40-85% w/w sodium salt of racemic ibuprofen and 5-15% w/w sodium carbonate or bicarbonate.

35. (Withdrawn) The method according to claim 11 wherein the dosage has a crushing strength in the range 8-12Kp at a compression force in the range 100-140MPa.

36. (Withdrawn) The method according to claim 11 wherein the solid dosage form has a disintegration time in the range of up to 5 minutes.

37. (Withdrawn) A process according to claim 20 wherein the solid dosage form has a crushing strength in the range 8-12Kp when compressed at a compression force in the range 100-140Mpa.

38. Cancelled

39. (Currently Amended) A solid non-effervescent coated compressed dosage form adapted for direct oral administration by swallowing and adapted to disintegrate quickly in the gastro-intestinal tract, comprising a racemic ibuprofen medicament in the form of the sodium salt present to an extent of 35% or more by weight of the dosage form and in homogeneous admixture with a carrier material comprising

- i) a compressible filler component combined with a disintegrating component;
- ii) 3-20% solid sodium carbonate ~~or sodium bicarbonate~~ by weight of the dosage form; wherein the dosage form is obtained by compressing said racemic ibuprofen medicament and said carrier material at a compression force above 80 MPa such that said dosage form has a crushing strength in the range 6.5-15 Kp and a disintegration time of less than 10 minutes, and then coating the compressed product, and provided that the ibuprofen medicament does not contain a calcium salt of ibuprofen in combination with an alkali metal salt of ibuprofen.

40. (Previously Presented) A dosage form according to claim 39 comprising a compressible filler component and up to 15% of a discrete disintegrant component by weight of the dosage form.

41. (Currently Amended) A dosage form according to claim 39 comprising 5-15% sodium carbonate ~~or sodium bicarbonate~~ by weight of the dosage form.

42. (Currently Amended) A dosage form according to claim 39 comprising sodium carbonate ~~or bicarbonate~~ in a weight ratio to the racemic ibuprofen medicament of 1:2 to 1:10.

43. (Previously Presented) A dosage form according to claim 39 wherein the compressible filler component comprises microcrystalline cellulose, lactose, mannitol or mixtures thereof.

44. (Previously Presented) A dosage form according to claim 39 wherein the disintegrating component comprises croscarmellose sodium, sodium starch glycolate or mixtures thereof.

45. (Previously Presented) A dosage form according to claim 39 in the form of a compressed tablet.

46. (Currently Amended) A dosage form according to claim 39 in the form of a compressed tablet comprising 40-60% sodium salt of ibuprofen by weight of the dosage form, 20-50% one or more compressible fillers by weight of the dosage form, up to 10% of a disintegrant component by weight of the dosage form selected from croscarmellose sodium and sodium starch glycolate, 4-16% of sodium carbonate ~~or bicarbonate~~ by weight of the dosage form, up to 4% lubricant by weight of the dosage form and up to 2% flow aid by weight of the dosage form.

47. (Previously Presented) A dosage form according to claim 39 wherein the compressible filler component is selected from one or more of methyl cellulose, hydroxymethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, microcrystalline cellulose, hydroxypropylmethyl cellulose, hydroxymethylpropyl cellulose phthalate, lactose, sucrose, dextrin, sodium chloride, mannitol, sorbitol cyclodextrin, maltodextrin, calcium phosphate and calcium sulphate.

48. (Withdrawn) A method of obtaining an onset-hastened analgesic and/or anti-pyretic response comprising the oral administration of a non-effervescent compressed solid dosage form adapted to disintegrate quickly in the gastrointestinal tract comprising 35% or more by weight of a racemic ibuprofen medicament in the form of the sodium salt in homogeneous admixture with a carrier material comprising:

- i) a compressible filler component combined with a disintegrating component and
- ii) 3-20% solid sodium carbonate or sodium bicarbonate by weight of the dosage form.

wherein the dosage form is obtainable by compressing said racemic ibuprofen medicament and said carrier material at a compression force above 80 MPa such that said dosage form has a crushing strength in the range of 6.15-15Kp and a disintegration time of less than 10 minutes,

provided that the ibuprofen medicament does not include a calcium salt of ibuprofen in combination with an alkali metal salt of ibuprofen.

49. (Withdrawn) A method according to claim 48 wherein the dosage form has a crushing strength in the range of 8-12 Kp, at a compression force in the range of 100-140 MPa.

50. (Withdrawn) A method according to claim 48 wherein the solid dosage form has a disintegration time in the range of 1-5 minutes.

51. (Withdrawn) A method according to claim 48 wherein the dosage form is in the form of a directly compressed tablet comprising 40-85% sodium salt of ibuprofen by weight of the dosage form and 5-15% sodium carbonate or bicarbonate by weight of the dosage form.

52. (Currently Amended) A solid formulation adapted for direct oral administration by swallowing and adapted to disintegrate quickly in the gastro-intestinal tract, said solid formulation having a coating layer and a core comprising a compressed composition comprising a racemic ibuprofen medicament in the form of the sodium salt in homogeneous admixture with a carrier material, the racemic ibuprofen medicament being present to an extent of 35% or more by weight of the composition and the carrier material comprising a compressible filler component combined with a disintegrating component characterized in that the carrier material comprises 3-20% solid sodium carbonate ~~or sodium bicarbonate~~ by weight of the dosage form, wherein the compressed composition is obtainable by compressing said racemic ibuprofen medicament and said carrier

material at a compression force above 80 MPa to provide a layer having a crushing strength in the range of 6.5-15 Kp and a disintegration time of less than 10 minutes.

53. (Currently Amended) A solid non-effervescent coated compressed dosage form adapted for direct oral administration by swallowing and adapted to disintegrate quickly in the gastro-intestinal tract comprising a racemic ibuprofen medicament in the form of the sodium salt present to an extent of 35% or more by weight of the dosage form and in homogeneous admixture with a carrier material comprising

- a. a compressible filler component combined with a disintegrating component;
- b. 3-20% solid sodium carbonate ~~or sodium bicarbonate~~ by weight of the dosage form;

wherein the carrier is present in an amount of 45 to 55% by weight based on the total weight of the dosage form and the dosage form is obtainable by compressing said racemic ibuprofen medicament and said carrier material at a compression force above 80 MPa such that said dosage form has a crushing strength in the range 6.5-15 Kp and a disintegration time of less than 10 minutes, and then coating the compressed product, and provided that the ibuprofen medicament does not contain a calcium salt of ibuprofen in combination with an alkali metal salt of ibuprofen.

54. (Previously Presented) A dosage form according to claim 39, wherein the dosage form is film-coated.

55. (Previously Presented) A solid formulation according to claim 52, wherein the solid formulation is film-coated.

56. (Previously Presented) A dosage form according to claim 53, wherein the dosage form is film-coated.

57. (Previously Presented) A solid non-effervescent compressed dosage form adapted for direct

oral administration by swallowing and adapted to disintegrate quickly in the gastro-intestinal tract, comprising a racemic ibuprofen medicament in the form of the sodium salt present to an extent of 35% or more by weight of the dosage form and in homogeneous admixture with a carrier material comprising

- I) a compressible filler component combined with a disintegrating component;
- ii) 3-20% solid sodium carbonate by weight of the dosage form;
wherein the dosage form is obtained by compressing said racemic ibuprofen medicament and said carrier material at a compression force above 80 MPa such that said dosage form has a crushing strength in the range 6.5-15 Kp and a disintegration time of less than 10 minutes, provided that the ibuprofen medicament does not contain a calcium salt of ibuprofen in combination with an alkali metal salt of ibuprofen.

58. (Previously Presented) A dosage form according to claim 57 comprising a compressible filler component and up to 15% of a discrete disintegrant component by weight of the dosage form.

59. (Previously Presented) A dosage form according to claim 57 comprising 5-15% sodium carbonate by weight of the dosage form.

60. (Previously Presented) A dosage form according to claim 57 comprising sodium carbonate in a weight ratio to the racemic ibuprofen medicament of 1:2 to 1:10.

61. (Previously Presented) A dosage form according to claim 57 wherein the compressible filler component comprises microcrystalline cellulose, lactose, mannitol or mixtures thereof.

62. (Previously Presented) A dosage form according to claim 57 wherein the disintegrating component comprises croscarmellose sodium, sodium starch glycollate or mixtures thereof.

63. (Previously Presented) A dosage form according to claim 57 in the form of a compressed tablet.

64. (Currently Amended) A dosage form according to claim 57 in the form of a compressed tablet comprising 40-60% sodium salt of ibuprofen by weight of the dosage form, 20-50% one or more compressible fillers by weight of the dosage form, up to 10% of a disintegrant component by weight of the dosage form selected from croscarmellose sodium and sodium starch glycolate, 4-16% of sodium carbonate ~~or bicarbonate~~ by weight of the dosage form, up to 4% lubricant by weight of the dosage form and up to 2% flow aid by weight of the dosage form.

65. (Previously Presented) A dosage form according to claim 57 wherein the compressible filler component is selected from one or more of methyl cellulose, hydroxymethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, microcrystalline cellulose, hydroxypropylmethyl cellulose, hydroxymethylpropyl cellulose phthalate, lactose, sucrose, dextrin, sodium chloride, mannitol, sorbitol cyclodextrin, maltodextrin, calcium phosphate and calcium sulphate.

66. (Previously Presented) A dosage form according to claim 57, wherein the dosage form is coated.

67. (Previously Presented) A dosage form according to claim 57, wherein the dosage form is film-coated.

68. (Previously Presented) A solid formulation adapted for direct oral administration by swallowing and adapted to disintegrate quickly in the gastro-intestinal tract, said solid formulation having a layer comprising a compressed composition comprising a racemic ibuprofen medicament in the form of the sodium salt in homogeneous admixture with a carrier material, the racemic ibuprofen medicament being present to an extent of 35% or more by weight of the composition and

the carrier material comprising a compressible filler component combined with a disintegrating component characterized in that the carrier material comprises 3-20% solid sodium carbonate by weight of the dosage form, wherein the compressed composition is obtainable by compressing said racemic ibuprofen medicament and said carrier material at a compression force above 80 MPa to provide a layer having a crushing strength in the range of 6.5-15 Kp and a disintegration time of less than 10 minutes.

69. (Previously Presented) A formulation according to claim 68, wherein the formulation is coated.

70. (Previously Presented) A formulation according to claim 68, wherein the formulation is film-coated.

71. (Previously Presented) A solid non-effervescent compressed dosage form adapted for direct oral administration by swallowing and adapted to disintegrate quickly in the gastro-intestinal tract comprising a racemic ibuprofen medicament in the form of the sodium salt present to an extent of 35% or more by weight of the dosage form and in homogeneous admixture with a carrier material comprising

- a. a compressible filler component combined with a disintegrating component;
- b. 3-20% solid sodium carbonate by weight of the dosage form;

wherein the carrier is present in an amount of 45 to 55% by weight based on the total weight of the dosage form and the dosage form is obtainable by compressing said racemic ibuprofen medicament and said carrier material at a compression force above 80 MPa such that said dosage form has a crushing strength in the range 6.5-15 Kp and a disintegration time of less than 10 minutes, provided that the ibuprofen medicament does not contain a calcium salt of ibuprofen in combination with an alkali metal salt of ibuprofen.

Serial Appln. No.: 09/125,114
Response dated October 24, 2005
Reply to Office Action of June 24, 2005

72. (Previously Presented) A dosage form according to claim 71, wherein the dosage form is coated.

73. (Previously Presented) A dosage form according to claim 71, wherein the dosage form is film-coated.